

IV. THE DATA COLLECTION PROCESS

A. Getting Started

Your job on Project HOPE begins when a participating clinic notifies you, the Evaluation Team at Children's National Medical Center, that an eligible woman has agreed to participate in the study. This means that she has been:

- Approached at the clinic and screened for eligibility. To be eligible she needs to be (1) 28 weeks pregnant or less, (2) a DC resident, (3) 18 years of age or older, (4) African-American or Latina, and (5) English-speaking.
- Determined to have one or more of the following risk factors identified from the screening questionnaire: smokes cigarettes or is exposed to tobacco smoke, is depressed, and/or is abused by her partner.
- Determined to be not suicidal.
- Informed of all aspects of the study and agrees to participate in the study.

1. The Face Sheet

The Pregnancy Advisor Assistants (PAAs), who are responsible for approaching, screening, and recruiting women at the clinic sites, will complete a Face Sheet (see Exhibits IV-1 and IV-2) for each eligible woman with risk who agrees to participate. In later phases of the study, PAAs will enter the Face Sheet information into the Data Management System (DMS), and, through nightly transmissions, this information will be sent to Children's National Medical Center. You will then just need to print the new, incoming Face Sheets each morning from the DMS. Until then, however, PAAs will fax the Face Sheets to Children's Hospital as they are completed. Receipt of a completed Face Sheet begins your involvement with a participating woman.

The completed Face Sheet has all of the information you need to contact the participating woman, including:

- Her Subject ID number (this number is assigned when a woman's information is entered into the DMS the first time)
- Her name and address
- Her home phone number and other numbers where she can be reached, including the type (cell phone, pager, etc.), in whose name the number is listed, and that person's relationship to the woman.

EXHIBIT IV-1
Face Sheet (Side One)

EXHIBIT IV-2
Face Sheet (Side Two)

- The best time to call her
- Whether it is all right to leave her a message if she is unavailable (This is explained in Chapter II.)
- The date and time of the appointment to conduct the baseline interview that the PAA arranged after recruiting her
- The date of her next prenatal care appointment
- The names and contact information of up to three people who would know how to contact the woman
- The participating woman's date of birth
- The number of weeks pregnant she was at the time of recruitment
- The baby's due date
- Other clinics she has attended for this pregnancy

When a completed Face Sheet is received at Children's, you will first enter selected information from the Face Sheet into the DMS:

- The date the woman was recruited
- Her full name
- The number of weeks pregnant she was at the time of recruitment
- Her next prenatal care visit appointment

By doing so, you will establish a Children's National Medical Center record for the woman in the DMS. However, all of the information on the Face Sheet will be entered into the DMS at the clinic.

The complete Face Sheet information will be available for you to access, including the contact information. Eventually this will be accomplished through nightly transmissions from each clinic to Children's. Initially, however, the complete Face Sheet information will be sent to the computer at Children's every two weeks or so. Due to this time lag, you will have to rely on the contact information documented on the hardcopy Face Sheet that is faxed to Children's from each clinic. If this information is no longer up-to-date when you are trying to contact a woman, you will need to telephone the clinic project staff for any updated contact information they may have.

As a woman's involvement in the study progresses, you will be updating her record in the DMS by entering final results for each of the evaluation interviews -- baseline, prenatal follow-ups and postpartum follow-up. Clinic staff will also be updating evaluation activities in the woman's record, including collection of saliva specimens and disbursements of evaluation compensation. In addition, clinic project staff will be updating contact information for a woman as it is obtained.

After each evaluation interview, you, also, will be updating contact information for each woman, using the Locator Information Update Form that is generated by the DMS. When you obtain updated contact information, you will fax this information to the clinic project staff. They, in turn, will enter the updated information into the DMS. Eventually, this updated contact information entered by the clinics will be available for you to access after nightly transmissions from each clinic to Children's. Initially, however, the updated information will be sent to the computer at Children's every two weeks or so. You will be able to view the evaluation activities that have been completed for a participating woman by the clinic staff, as well as the most current contact information. Likewise, the clinic sites will be able to view the evaluation interview activities that have been completed by you for a participating woman.

Establishing a record in the DMS will also trigger the scheduling program that uses the next prenatal care appointment to monitor the "window" of time in which the baseline evaluation interview must be completed. For the follow-up evaluation interviews, the DMS will use gestational age to monitor the "window" of time to complete these interviews. (The "window of time" is explained Section F of this chapter.) The DMS will generate a daily report indicating the number of days left to complete an evaluation interview before the end of the window for individual women. This will tell you how much time there is to contact a woman and complete an evaluation interview. If the interview is not completed within that "window" of time, the DMS will automatically "close" the case and deem the woman as "unavailable".

2. Initiating a File Folder

The next step to take is to initiate a file folder for the participating woman. First you will generate from the DMS a page of labels of her Subject ID Number. (This procedure is explained in Chapter VI.) These labels will be affixed to all forms that are generated for the woman, as are discussed throughout this chapter. A label should also be affixed to the outside of the file folder. To prepare you for contacting the woman to administer the baseline interview, affix a label on a blank Baseline Evaluation Questionnaire and place it in the folder. Finally, you will initiate an Evaluation Contact Booklet (see Appendix C) which is used to document activities related to the administration of the evaluation questionnaires. Completing the Evaluation Contact Booklet is discussed in the next section.

B. The Evaluation Contact Booklet

1. Section A. Information About the Participant

The front page of the Evaluation Contact Booklet contains information that is obtained on the Face Sheet. Affix a Subject ID label and record today's date, the site from which the woman was recruited, and the date the woman was recruited at the site on the top of the front page of the booklet. Then complete "Section A. Information About the Participant" by recording:

- The woman's name and address
- Her home phone number and other numbers where she can be reached, including the type (cell phone, pager, etc.), in whose name the number is listed, and that person's relationship to the woman
- The best time to call her
- Whether it is all right to leave her a message if she is unavailable (This is explained in Chapter II.)
- The date and time of the appointment to conduct the baseline interview, as well as the best number to reach her, as arranged by the PAA at the time of recruitment
- Her next prenatal care appointment
- The participating woman's date of birth
- The number of weeks pregnant she was at the time of recruitment
- The baby's due date
- Other clinics she has attended for this pregnancy

Be sure to file the Face Sheet pages in the woman's folder so that you have access to the contact information obtained by the clinic project staff.

The inside of the booklet consists of the following sections:

2. Section B. Result Codes

The result codes provided in Section B should be used to code the outcome for each evaluation interview. For most pending situations that you encounter, such as “no one home” or “trying to locate,” a pending code will not be assigned. You will simply describe these pending situations in Section E and not enter anything into the DMS. Until you assign a final result code to the case, the DMS will “assume” that it is still being worked.

There are three pending situations, however, for which a pending result code will be assigned and entered into the DMS:

- 050 REVISED APPOINTMENT DATE: If a new, specific appointment to conduct an evaluation interview has been arranged, record this code and the new appointment in Section E and enter it into the DMS. So that the “window” of time to conduct the interview can be monitored by the DMS, the new appointment date must also be entered into the system. The DMS will issue a report on that day indicating that an appointment for that day has been arranged. If the newly arranged appointment is on a date that is beyond the “window”, the DMS will keep the case “opened” through the newly arranged appointment date. Do not assign this code for vague reschedules, such as “call back later.”
- 051 SENT TO TRACING: Use this code if you are conducting tracing activities (see Section G of this chapter) in an effort to locate a participating woman for the interview. Record this code in Section E and enter it into the DMS. If you are unable to locate the woman, you will finalized it as “Unable to Locate” (code 151).
- 052 SET DATE TO EXTEND WINDOW: If the “window” of time for conducting an interview is running out and it would be appropriate to extend the window, record this code in Section E and enter it into the DMS. You must obtain supervisory approval to assign this code, enter it into the DMS and extend the window date.

The final result codes are:

- 001 INTERVIEW COMPLETED: Assign this code in Section C and enter it into the DMS when you have completed an evaluation interview. The DMS will “ask” you whether you are entering this code for a baseline interview, 22-26 week prenatal follow-up interview, 34-38 week prenatal follow-up interview, or postpartum interview.
- 002 INTERVIEW PARTIALLY COMPLETED: Assign this code in Section C and enter it into the DMS when the interview is only partially completed and you were never able to reach the woman to complete it. Explain the circumstances in Section D of the Evaluation Contact Booklet. The DMS will “ask” you whether you are entering this code for a baseline interview, 22-26 week prenatal follow-up interview, 34-38 week prenatal follow-up interview, or postpartum interview.

- 151 UNABLE TO LOCATE, FINAL: Assign this code in Section C and enter it into the DMS when your tracing efforts have been unsuccessful. The DMS will prompt you to indicate whether this is for the baseline interview, 22-26 week prenatal follow-up interview, 34-38 week prenatal follow-up interview, or postpartum interview. If it is the baseline interview, the woman will be dropped from the study and will not be able to participate. If it one of the prenatal follow-up interviews, her “window of time” will reopen for the next scheduled interview, and she will not be given the \$15 compensation payment for the incomplete interview.
- 152 SUBJECT UNAVAILABLE: Assign this code in Section C when you have been unable to contact the woman to administer the interview within the “window” of time. Explain the circumstances in Section D of the Evaluation Contact Booklet. You do not have to enter this code into the DMS. Unless the window has been extended (Code 052) or a new appointment beyond the window has been entered (Code 050), the DMS will automatically close this case when the window of time has expired and label it as “Unavailable”. The DMS will prompt you to indicate whether this is for the baseline interview, 22-26 week prenatal follow-up interview, 34-38 week prenatal follow-up interview, or postpartum interview. If it is the baseline interview, the woman will be dropped from the study and will not be able to participate. If it one of the prenatal follow-up interviews, her “window of time” will reopen for the next scheduled interview, and she will not be given the \$15 compensation payment for the incomplete interview.
- 153 OTHER FINAL OUTCOME: Assign this code in Section C and enter into it into the DMS for any other final outcome that results from an attempt to administer an evaluation interview. Explain the circumstances in Section D of the Evaluation Contact Booklet. The DMS will prompt you whether this is for a baseline interview, 22-26 week prenatal follow-up interview, 34-38 week prenatal follow-up interview, or postpartum interview. If it is the baseline interview, the woman will be dropped from the study and will not be able to participate. If it one of the prenatal follow-up interviews, her “window of time” will reopen for the next scheduled interview, and she will not be given the \$15 compensation payment for the incomplete interview.
- 901 REFUSED: Assign this code in Section C and enter it into the DMS when the participating woman refuses to be interviewed. Explain the circumstances in Section D of the Evaluation Contact Booklet. The DMS will prompt you to indicate whether this is for a baseline interview, 22-26 week prenatal follow-up interview, 34-38 week prenatal follow-up interview, or postpartum interview. If it is the baseline interview, the woman will be dropped from the study and will not be able to participate. If it one of the prenatal follow-up interviews, her “window of time” will reopen for the next scheduled interview, and she will not be given the \$15 compensation payment for the incomplete interview.

- 902 NOT APPLICABLE: This code is assigned in Section C for a prenatal follow-up interview in the event that the woman's pregnancy ends early. You would also explain the circumstances in Section D of the Evaluation Contact Booklet. In the DMS, rather than entering this code, you will be prompted to enter the delivery date (or pregnancy end date if the pregnancy did not result in a live birth). The DMS will also prompt you whether this is for a 22-26 week prenatal follow-up interview or 34-38 week prenatal follow-up interview. For example, if you are contacting a woman to administer the 34-38 week prenatal follow-up interview and you find out that she delivered prematurely, you would administer the postpartum interview and assign this code to the 34-38 week prenatal follow-up interview in the Evaluation Contact Booklet. In the DMS you will only need to enter the delivery date. The DMS will automatically label the 34-38 week prenatal follow-up interview as "Not Applicable."

3. Section C. Final Result Information

Complete the information in Section C of the Evaluation Contact Booklet for each evaluation interview that has been assigned a final result code. The only circumstance in which you would not complete this information for a specific evaluation interview is if the woman terminates from the study early (e.g, she refuses to do the baseline and therefore she is terminated from the study). For each evaluation interview, record:

- Your 2-digit interviewer ID number,
- The final result code, and
- The date the final result code was assigned.

4. Section D. Non-interview Report

In this section, explain why you were not able to complete the interview. Specifically, an explanation is needed if you assign codes 002, 152, 153, 901, and 902. Be complete in describing the situation so you can accurately discuss the details with your supervisor.

5. Section E. Appointment and Contact Log

This section is used to document all contacts made with a participating woman to administer an evaluation interview. This includes any attempted or actual contacts with a person, including other persons who answer the telephone. Record each contact, or attempted contact, on a separate line. For example, if you telephone and no one answers, and then you telephone again, an hour later, you must record both contact attempts. For each contact attempt, record:

- Date
- Day of the week
- Time
- Your 2-digit interviewer ID number
- Comments to explain the result of the contact attempt.

C. Conducting the Baseline Interview

Although eligible women with one or more risk factors may agree to participate in the project at the clinic when they are recruited by the PAA, only women who complete the Baseline Evaluation Interview will actually be randomized to either intervention or usual care group. At the time a woman is recruited into the study, the PAA will arrange an appointment for you to administer the Baseline Evaluation Questionnaire. The PAA will be instructed to identify a date and time as soon as possible after recruitment so that (1) the baseline interview can be completed, (2) the woman can be randomized into the intervention or usual care group, and (3) the woman can be notified of the results of the randomization. All of these activities need to occur before the woman's next prenatal care appointment. In most cases and depending on gestational age, this "window of time" will be one month. If you are having difficulty in getting a woman to commit to do the baseline interview, it is important that you explain that she cannot participate in Project HOPE unless the interview is completed before her next prenatal care appointment.

When you have completed the Baseline Evaluation Interview you should immediately enter the final result code, 001, in the DMS. On a daily basis, the DMS will generate a report of each woman's final baseline result, sorted by clinic site. You will print this report and fax it to the clinics. For women who have completed the baseline interview, the PAA at the clinic site will input the completed interview result code, 001, into the DMS, which, in turn, will trigger a program to randomize each woman into the intervention or usual care group. In later phases of the project, this procedure will be automated, so that final baseline result information that is input at Children's will be transmitted to each clinic site on a nightly basis to trigger the randomization program. The PAA will then contact each participating woman and inform her of the randomization results so that, if she is in the intervention group, she can prepare to stay longer when she comes in for her next prenatal care appointment.

D. Conducting Follow-up Evaluation Interviews

1. Prenatal Follow-up Interviews

The points in time when prenatal follow-up evaluation interview will be administered to a participating woman are:

- At approximately 22-26 weeks gestation (end of the second trimester)
- At approximately 34-38 weeks gestation (third trimester)

A minimum interval of 4 weeks will be maintained between each interview.

To be eligible for the study, women must be no more than 28 weeks pregnant at time of recruitment. Therefore, women who are at this outer limit of gestational age when they are recruited will be administered one prenatal follow-up interview, during the third trimester, in addition to the baseline and postpartum interviews. Women who are recruited earlier in their pregnancy will be administered two prenatal follow-up interviews, in addition to the baseline and postpartum interviews.

The DMS will identify women who need a prenatal follow-up interview based on their gestational age, and women who need a postpartum interview based on their delivery date (or pregnancy end date if the pregnancy outcome was not a live birth). The DMS will generate a report of those women who must be scheduled for an interview as they reach the appropriate time window. You will then contact the women and schedule an appointment for the appropriate follow-up interview.

2. Postpartum Follow-up Interviews

A postpartum follow-up evaluation interview will be administered 6 to 10 weeks after the delivery date. The DMS will identify women who need a postpartum interview based on their delivery date (or pregnancy end-date if the pregnancy outcome was not a live birth). Once a delivery date has been entered into the DMS, the system will begin the calculation to “open” the “window of time” so that an appointment for the postpartum follow-up interview can be arranged.

The determination of when a woman’s pregnancy has ended can come from different sources, such as the clinic project staff or you. However, in order to ensure that a woman’s pregnancy end date is systematically determined, the PAAs at each clinic will be responsible for finding out this information. Using the pregnancy due date obtained at the time of a woman’s recruitment into the study, the DMS will generate a report for those women for whom a delivery date has not been entered. When a woman’s name appears on this report it will indicate to the PAAs that her delivery is eminent and it is time to find out whether it has occurred. If so, the PAA will enter the delivery date into the DMS. This will cause the DMS to trigger the opening of the “window of time” to conduct the postpartum follow-up interview at the appropriate time.

It is probable, however, that early termination of a pregnancy will be discovered ad hoc. That is, clinic project staff may discover it or you may find out when you contact the woman to schedule or administer a prenatal follow-up interview. Entry of the end of pregnancy date into the DMS will make this information available to everyone.

If you do find out, you will need to ask the woman the date her pregnancy ended. If it has been at least 6 weeks, you will immediately try to administer the postpartum follow-up interview. If it has not been at least six weeks, you will try to arrange a callback at that time, and then enter the pregnancy end date into the DMS so that the scheduling mechanism can be triggered. In any case, you will need to be sensitive to the situation, especially if the pregnancy did not end in a live birth. As is indicated in Chapter III, if the pregnancy did not end in a live birth, questions on the postpartum follow-up questionnaire that are marked with an “X” will not be asked.

E. Concluding Evaluation Interview Activities

1. Updating the Contact Information

After the conclusion of each evaluation interview, you will be updating contact information that will be used to locate her. After the baseline interview, you will use the hardcopy Face Sheet for this activity. After the prenatal follow-up interviews, you will generate a summary of the contact information from the DMS for this activity. When updating contact information, you need to:

- verify whether the existing information is still accurate
- try to obtain information that is missing
- determine whether any new information should replace existing information

The contact information that you will be updating will be:

- the woman's name and address
- the telephone numbers where she can be reached
- the names and contact information for up to three people who would know how to reach her

Whenever you make any changes to the contact information, you will need to fax the hardcopy form on which you have documented the changes to the clinic sites. Clinic project staff will be responsible for updating the contact information in the DMS. Eventually, this updated contact information entered by the clinics will be available for you to access after nightly transmissions from each clinic to Children's. Initially, however, the updated information that is entered into the DMS at the clinic sites will be sent to the computer at Children's every two weeks or so.

2. Arranging for Saliva Collection and Compensation Disbursement

When you have completed administering the evaluation interview and updated the contact information on the Face Sheet after the baseline interview and on the Locator Update Information Form after the follow-up interviews, you must remind the woman that participation in the study also includes the collection of a saliva specimen after each evaluation interview. The collection of the specimen is done at the clinic site where she was recruited. She can choose to provide the specimen the next time she goes to the clinic for a prenatal care visit, or sooner. At that time she will also be given the \$15 compensation payment for completing the evaluation interview. As appropriate, you should also remind her that you will be calling her in the next trimester or of her pregnancy or after she delivers to arrange an appointment to conduct another interview. You should learn the following script to end your contact with a participating woman:

That's all the questions I have. I would like to remind you that during your next prenatal care appointment at (NAME OF RECRUITMENT CLINIC), a member of Project HOPE will ask you to provide a saliva sample and will give you \$15 for completing today's interview. Of course, if you want to go to the clinic sooner, that would be all right. Also, it is possible that my supervisor will call you to make sure that I have done my job correctly.

IF APPROPRIATE: I will be calling you again to set up an appointment for another interview (in your next trimester/after your delivery)

IF APPROPRIATE: Please make sure to keep the show cards that we used during the interview in a safe place because we will be using them again during the next interview.

Thank you very much for your time.

3. Documenting and Reporting Results

When you have completed your contact with the participating woman, you should immediately edit the completed forms (see Chapter VI) and complete Section C and, if appropriate, Section D of the Evaluation Contact Booklet. Then, you must enter the final result information into the DMS.

4. Finalizing the File Folder

After you have edited the evaluation questionnaire, you will make a photocopy. Your supervisor will arrange to federal express the original copy of the questionnaire to Research Triangle Institute for processing. The photocopy will remain in the woman's file folder. Updated contact information that has been documented on hardcopy, (Face Sheet or Locator Update Information Form), will be faxed to the clinic sites where the information will be entered into the DMS. Then, file the folder in the designated area at Children's for availability to conduct the next evaluation interview.

F. Monitoring the "Window of Time"

The DMS will monitor the "window of time" for each evaluation interview for each woman and report the number of days left in which the interview must be completed. When the time has elapsed, it will automatically "close" the window and the evaluation interview for that woman will be finalized as "Unavailable." The only way that a case can remain open beyond the "window of time" is if you enter a newly arranged appointment that is beyond the window, or if you extend the window of time.

The DMS will produce three reports to help you keep scheduled appointments and ensure the evaluation interviews are conducted within the allowed “window of time.” These reports will include relevant information about each woman, such as her Subject ID number, name, the type of interview to conduct, time and date of appointment, number of days left in the window of time, etc. They are:

- A report of women with appointments today, which can be sorted by interviewer and time of appointment. An example is shown in Exhibit IV-3.
- A report of women with future appointments, which can be sorted by interviewer and date of appointment.
- A report of women with no appointments, which will be sorted by number of days left in the “window”. An example is shown in Exhibit IV-4. If the window of time runs out for a particular evaluation interview, these women will reappear when the window of time starts for their next evaluation interview.

When you ask the DMS to run these or any other reports, the first action the system will take is to review each case and “open” or “close” its “window”, as appropriate. Once a window is “closed”, you will not be allowed to enter any final result code for that case. Therefore, it is always best to enter all final result codes before running reports in the DMS.

G. Tracking Procedures

Despite the efforts that are in place to obtain locating information, it is likely that we will still lose contact with some participating women. You will be responsible for trying to locate women for the purposes of conducting the evaluation interviews. If you are having trouble making contact with a participant, you should use the following steps to locate her. These steps for participant tracking are listed in sequential order. Start with Steps 1 and 2, and proceed each subsequent step only if your efforts to contact the participant are not successful.

Step 1: Check the HOPE contact information database to obtain the most up-to-date information. Print the Locator Update Information Form from the Data Management System.

Step 2: Telephone the participant at her primary telephone number. If the woman is no longer available at this number, ask for and dial a forwarding telephone number. If the phone is disconnected or you cannot obtain a forwarding number, go to Step 3.

Step 3: Telephone the participant at the secondary telephone numbers (e.g., cell phone, work number, beeper number, other number where she can be reached) listed for her.

Step 4: Telephone Directory Assistance for a new listing for the participant. If she originally provided the name of another person under which her telephone number is listed, check Directory Assistance for a new listing for that person.

EXHIBIT IV-3
“Appointment Today” Report

EXHIBIT IV-4
“No Appointment” Report

Step 5: Check with clinic staff for updated or different contact information for the participant.

Step 6: Telephone relatives and/or friends provided by the participant as secondary contact sources.

Step 7: (Tentative) Submit request to RTI Tracing Operations to check tracing databases using available information about the study participant, e.g., name, address, previous phone numbers.

If, at any point, you locate the woman at a new telephone number, you must update her locator information in the Data Management System. If, however, you have exhausted all of these resources and are still not able to locate the participant, the participant is considered to be lost. However, we may implement one further step for tracking, as noted above in Step 7. Eventually, you may be able to contact RTI Tracing Operations and let them know that you are unable to locate this woman. They will continue the tracking procedures and advise you of the result of their efforts. Please note that this step is still tentative at this time. If this procedure is operationalized, we will provide additional information on how to contact RTI Tracing Operations.

Note that clinic project staff will also be attempting to locate study participants for intervention and other follow-up (saliva samples, compensation disbursements), and will follow these same steps in their tracking efforts. However, due to the Project firewall, you may not make contact with clinic staff to locate the participants. Thus, if Step 5 is required, you will contact the clinic project staff, who will speak to clinic staff and the hospital delivery site and relay the results of their inquiry back to you.

H. Compensation

Participation in Project HOPE requires a considerable time commitment. In order to recruit the desired number of participants into the Project and, more importantly, to maintain their participation throughout their pregnancies and immediate postpartum periods, women are provided compensation for the various stages of recruitment and participation. We have referred to these compensations throughout the Manual, but this chapter provides a summary of the compensation package.

1. Recruitment Compensation

- Audio-CASI (Screening). All women who complete the Audio-CASI will receive \$5, regardless of the result of the interview. Depending upon the site, this money will be provided in cash, as a cash voucher, or as a food voucher. Women who initiate the Audio-CASI but do not complete the screening are not eligible to receive the money.
- Intervention Consent Form (Recruitment). All women who sign the Intervention Consent Form will receive 30-minute telephone card. The woman may use this card to contact Project staff, if necessary.

Women who receive the screening and recruitment compensations must indicate their acceptance of these gifts by signing a receipt that is issued by the PAA.

2. Evaluation Compensation

The participants will receive \$15 for completing each telephone interview. A woman may complete up to four interviews: the first at baseline, one in the second trimester (22-26 weeks), one in the third trimester (34-38 weeks), and one in the postpartum period. This money will be provided either in cash or as a cash voucher, depending upon the site. Note that the woman must successfully complete the interview in order to receive the compensation.

Each time an evaluation compensation is dispensed by the PAAs, they will ask the participant to indicate her acceptance of the gift by signing a receipt. The PAAs will check the DMS which will indicate whether the evaluation interview was completed. This information will be transmitted to the clinics after you have entered it into the DMS upon completion of an interview.

3. Intervention Compensation

- Prenatal Intervention Sessions. Women will receive \$10 for attending each prenatal intervention session. Depending upon site requirements, this compensation will be provided in cash or as a cash voucher.
- Postpartum Intervention Sessions. All participants will receive \$10 for attending each of two postpartum intervention sessions. This compensation will be provided in cash or as a cash voucher. In addition, participants will be given gift certificates for their babies. Those who attend their first postpartum intervention session will receive a \$15 gift certificate, redeemable at a CVS store. Those who attend their second postpartum visit will receive a \$25 gift certificate to CVS. The gift certificates will not be redeemable for cigarettes or alcohol.

4. Project Completion

All participants who complete the Project will be given a thank you letter and a coupon for a family portrait or baby pictures. This gift will be given to the women after the completion of the postpartum interview when she presents at the clinic to provide her saliva sample. It is provided in addition to the money for completing the interview itself.